



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day-22-21IE]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled "Understanding Health System Approaches to Chronic Pain Management" to the Office of Management and Budget (OMB) for review and approval. CDC previously published a "Proposed Data Collection Submitted for Public Comment and Recommendations" notice on Sept 27, 2021 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

- (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639-7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under 30-day Review - Open for Public Comments" or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street, NW, Washington, DC 20503 or by fax to (202) 395-5806. Provide written comments within 30 days of notice publication.

Proposed Project

Understanding Health System Approaches to Chronic Pain Management - New - National Center for Injury Prevention and

Control (NCIPC), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

CDC requests OMB approval for three years for this new data collection. This study is designed to evaluate the effects of evidence-based guidelines related to chronic pain management and opioid prescribing, including access to medications for opioid use disorder (MOUD), for patients and clinicians in primary care settings among a diverse sample of health systems.

Since 1999, nearly 841,000 people have died from drug overdose in the United States. Over 70% of drug overdose deaths in 2019 involved an opioid. From 1999 to 2019, nearly 247,000 people died in the United States from overdoses involving prescription opioids, with rates of deaths involving prescription opioids more than quadrupling from 1999 to 2019. In response, a range of clinical practice guidelines, policies, and regulations have been released in recent years to address the opioid overdose epidemic, with the goals of supporting safer opioid prescribing, improving diagnosis and treatment of OUD, and reducing overdose deaths in the United States.

To design this evaluation, we previously conducted and completed a "Feasibility Assessment of Health Systems" via surveys to determine the range of policies and guidelines being implemented by health systems, followed by an "evaluability assessment" by means of interviews with leaders of nine health systems. For the purposes of this evaluation, "Chronic pain

management policies/guidelines" refers to policies/guidelines that may include prescribing of opioid medications, nonpharmacologic therapies, and/or non-opioid medications for chronic pain, as well as OUD assessment and treatment.

In early 2020, CDC requested OMB approval for a Feasibility Assessment of Health Systems ("Feedback on the use of the CDC Guideline for Prescribing Opioids for Chronic Pain") through the "Generic Clearance for the Collection of Routine Customer Feedback" (OMB Control No. 0920-1050). This brief eligibility assessment consisting of surveys was sent to approximately 250 health systems to understand the landscape of health systems and the types of guidelines or policies implemented, and what strategies were used to do so. Of 250 health systems contacted, 46 responded and were considered for the following preliminary phase, the evaluability assessment. Among the 46 health systems who completed the feasibility assessment surveys, nine were selected for a more in-depth "evaluability assessment" based on several factors identified in the initial feasibility (survey) assessment, as well as other expert knowledge of potential systems.

The purpose of this data collection effort is to: (1) obtain an enhanced understanding of facilitators and barriers to guideline-concordant management of chronic pain and opioid prescribing (including access to MOUD) at the health system level, in order to improve patient outcomes while maximizing patient safety and to facilitate uptake by clinicians and health

systems, (2) describe unintended benefits and consequences to guideline/policy implementation, and (3) identify racial and ethnic disparities in guideline/policy implementation.

This mixed-methods, pre-post evaluation of health systems' implementation of chronic pain management and opioid prescribing policies/guidelines and the resultant outcomes requires both primary data collection (such as surveys, key informant interviews, focus groups, etc.) and secondary data collection (such as administrative, EHR, pharmacy dispensing, prescribing data, etc.) efforts to adequately answer the research questions. While secondary data (QI measures) from health system EHRs will provide longitudinal pre-post measures, primary data is needed to understand the characteristics and mechanisms of practice and patient change that can be attributed to the policies and guidelines.

CDC requests OMB approval for an estimated 577 annual burden hours. There are no direct costs to respondents other than their time to participate in the study.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hours)
Patient	Patient Survey	667	1	10/60
Treatment facility staff (Including primary care clinicians, health	Clinician Survey	1,313	1	10/60
	Invitation/ Follow up Email	1,980	2	3/60

system leaders, and other system staff and representatives)	System Leaders Interview Guide	17	1	1
	Case Study	30	1	30/60
	Member Checking Sessions	17	1	1

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